k081730

510(k) SUMMARY

Novel® Spinal Spacer System
510(k) SUMMARY
JUNE 2008

SEP 1 9 2008

**Company**: Alphatec Spine, Inc.
2051 Palomar Airport Road #100
Carlsbad, CA 92011 USA
Direct: (760) 494-6771
Fax: (760) 476-3468

**Contact Person**: Mary Stanners, Regulatory Affairs Specialist II

**Trade/Proprietary Name**: Novel® Spinal Spacer System

**Common Name**: Intervertebral Body Fusion Device

**Classification Name**: Orthosis, Spinal Intervertebral Fusion with Bone Graft, Cervical

**Classification Number(s)/Product Code(s)**: 21 CFR 888.3080 (ODP)

**Product Description**:

The Novel® Spinal Spacer System is an implantable device manufactured from PEEK and titanium alloy that is available in a variety of different shapes and sizes to suit individual pathology and anatomical conditions of the patient.

**Indications for Use:**

**When used as a Vertebral Body Replacement**

When used as a vertebral body replacement, the Novel® Spinal Spacer System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e. fracture). The Novel® Spinal Spacer System is intended for use with supplemental spinal fixation system. Specifically the Novel® Spinal Spacer System is to be used with Alphatec Zodiac Polyaxial Spinal Fixation System or the Alphatec Mirage Top Tightening Spinal System. Furthermore the Novel® Spinal Spacer System is intended for use with allograft.

**When used as a Lumbar Intervertebral Body Fusion**

When used as a lumbar Intervertebral Body Fusion, the Novel® Spinal Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic

back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The Novel® Spinal Spacer System is to be used with a supplemental fixation system and autogenous bone graft.

**When used as a Cervical Intervertebral Body Fusion**

When used as a cervical intervertebral body fusion device, the Novel® Spinal Spacer System is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone graft. These patients should have had six months of non-operative treatment. The Novel® Spinal Spacer System is to be used with a supplemental fixation system.

**Substantial Equivalence:**

Data was provided which demonstrated the Novel® Spinal Spacer System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, design, material and function.

**Performance Data**:

The test results demonstrate that the mechanical performance of the Novel® Spinal Spacer System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2008

Alphatec Spine, Inc.
% Ms. Mary Stanners
Regulatory Affairs Specialist II
5818 El Camino Real
Carlsbad, California 92008

Re: K081730
Trade/Device Name: Novel® Spinal Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP
Dated: September 12, 2008
Received: September 15, 2008

Dear Ms. Stanners:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

**510(k) Number (if known):** K081730

**Device Name:** Novel® Spinal Spacer System

***Indications for Use:***

**When used as a Vertebral Body Replacement**

When used as a vertebral body replacement, the Novel® Spinal Spacer System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e. fracture). The Novel® Spinal Spacer System is intended for use with supplemental spinal fixation system. Specifically the Novel® Spinal Spacer System is to be used with Alphatec Zodiac Polyaxial Spinal Fixation System or the Alphatec Mirage Top Tightening Spinal System. Furthermore the Novel® Spinal Spacer System is intended for use with allograft.

**When used as a Lumbar Intervertebral Body Fusion**

When used as a lumbar Intervertebral Body Fusion, the Novel® Spinal Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The Novel® Spinal Spacer System is to be used with a supplemental fixation system and autogenous bone graft.

**When used as a Cervical Intervertebral Body Fusion**

When used as a cervical intervertebral body fusion device, the Novel® Spinal Spacer System is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone graft. These patients should have had six months of non-operative treatment. The Novel® Spinal Spacer System is to be used with a supplemental fixation system.

Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K081730